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In Re: Patent Term Extension
Application for
U.S. Patent No. 4,965,204

NOTICE OF FINAL DETERMINATION - INELIGIBLE

The Johns Hopkins University ("Applicant"), the present owner of record of U.S. Patent No. 4,965,204 ("the '204 patent"), filed an application ("PTE Application") for extension of the term of the '204 patent under 35 U.S.C. § 156 in the United States Patent and Trademark Office ("USPTO") on August 31, 1999. Applicant sought extension based upon the premarket review under section 515 of the Federal Food, Drug, and Cosmetic Act ("FFDCA") of a medical device known by the tradename ISOLEX®300 and ISOLEX®300i. The Food and Drug Administration ("FDA") approved ISOLEX®300 and ISOLEX®300i for commercial use and sale on July 2, 1999.

A determination has been made that the '204 patent is **NOT** eligible for patent term extension under 35 U.S.C. § 156, because the PTE Application was not timely filed.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by Applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. § 1.136. See 37 C.F.R. § 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

The PTE Application was filed on August 31, 1999, as evidenced, for example, by the Certificate of Mailing by "Express Mail" pursuant to 37 C.F.R. § 1.10 included with the PTE Application. The Certificate indicates a Date of Deposit of August 31, 1999.

FDA approval triggers the time period specified in 35 U.S.C. § 156(d)(1), which requires that an application for patent term extension of a patent which claims a product, a method of using such product, or a method of manufacturing such product, wherein the product was subject to premarket regulatory review by a regulating agency, must be submitted, "within the sixty-day period beginning on the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use." See 35 U.S.C. § 156(d)(1) (emphases added). Additionally, the implementing regulations mirror the language of section 156(d)(1): "[t]he application is submitted within the sixty-day period beginning on the date the product first received permission for commercial marketing or use under the provision of law under which the applicable regulatory review period occurred . . . ." See 37 C.F.R. § 1.720(f) (emphases added).

The phrases used in section 156(d)(1) to define the time period, i.e., "within" and "beginning on" are clear. *See, Unimed, Inc. v. Quigg*, 888 F.2d 826, 828 (Fed. Cir. 1989) (characterizing the language used in section 156(d)(1) as "crystal clear"); *see also, United States v. Inn Foods, Inc.*, 383 F.3d 1319, 1322 (Fed. Cir. 2004) (explaining, in the context of a statute of limitation, that terms such as "within [a particular time period]" and "beginning on" clearly specify a time period and need no further analysis). Thus, under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, and the first day of that sixty-day period begins on the FDA approval date.

In the present case, the FDA approved PMA No. 97-0001 for the ISOLEX®300 and 300i

Magnetic Cell Selection System on July 2, 1999. The absolute deadline for filing the PTE Application was sixty days from July 2, 1999, starting the count of that sixty-day period on July 2, 1999. The sixtieth day of that time period was August 30, 1999 (a Monday). Applicant failed to meet the statutory deadline, because it filed the PTE Application on August 31, 1999, one day late. Consequently, the USPTO considers the PTE Application as untimely filed under § 156(d)(1) and § 1.720(f), and the PTE Application is dismissed.

At paragraph (5) on page 3 of the PTE Application, Applicant claims that the last day within the sixty day period permitted for submission of the PTE Application under 35 U.S.C. § 156 in compliance with 37 C.F.R. § 1.740(a)(5) is August 31, 1999. Specifically, Applicant asserts that "the last day within the sixty day period permitted for submission of an application for extension of a patent is 31 August 1999." For the reasons discussed above, however, Applicant has miscalculated the relevant time period. The absolute deadline for filing the PTE Application was August 30, 1999, or sixty days from July 2, 1999, starting the count of the sixty-day period on July 2, 1999. Thus, the USPTO considers the PTE Application as untimely filed under § 156(d)(1) and § 1.720(f), and the PTE Application is dismissed.

In a letter dated February 22, 2007, from FDA to USPTO concerning the present PTE Application, FDA states that "[t]he PMA was approved on July 2, 1999, which makes the submission of the patent term extension applications on August 31, 1999, timely within the meaning of 35 U.S.C. § 156(d)(1)." However, for the reasons discussed above, under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application was August 30, 1999, or sixty days from July 2, 1999, starting the count of the sixty-day period on July 2, 1999. Accordingly, the USPTO considers the PTE Application as untimely filed under § 156(d)(1) and § 1.720(f), and the PTE Application is dismissed.

Any correspondence with respect to this matter should be addressed as follows:

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By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: ISOLEX® 300 & 300i
FDA Docket No.: 1999E-5118